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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,525	04/01/2004	Tamara Byk	69222-A/JPW/DNS	4877

7590 09/29/2006

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New York, NY 10036

EXAMINER
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LI, QIAN JANICE

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/817,525	Applicant(s) BYK ET AL.	
	Examiner Q. Janice Li, M.D.	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S. C. 121:

- I. Claims 1-3 are drawn to a process for inducing proliferation of stem cells comprising administering to cultured stem cells a sFRP1 polypeptide. Classified in class 435, subclass 384.
- II. Claims 1-3 are drawn to a process for inducing proliferation of stem cells comprising administering to cultured stem cells an expression vector comprising sFRP1 gene. Classified in class 435, subclass 455.
- III. Claims 4-7 are drawn to a process for inducing proliferation of stem cells comprising culturing the stem cells with a second type of cells expressing a sFRP1 polypeptide. Classified in class 435, subclass 373.
- IV. Claims 8-14 are drawn to a method for treating a patient suffering from depletion of a cellular population comprising administering stem cells to the patient. Classified in class 424, subclass 93.1.
- V. Claims 15-20 are drawn to a method for treating a patient suffering from depletion of a cellular population comprising administering to the patient sFRP1 polypeptide. Classified in class 514, subclass 2.
- VI. Claims 15-20 are drawn to a method for treating a patient suffering from depletion of a cellular population comprising administering to the patient an

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- expression vector comprising the sFRP1 gene. Classified in class 514, subclass 44.
- VII. Claims 21, 22 are drawn to a pharmaceutical composition comprising a sFRP1 polypeptide. Classified in class 530, subclass 300.
- VIII. Claims 21, 22 are drawn to a pharmaceutical composition comprising an expression vector comprising the sFRP1 gene. Classified in class 435, subclass 320.1.
- IX. Claims 23 and 24 are drawn to a process for identifying a compound, which induces stem cell proliferation by modulating sFRP1 polypeptide. Classified in class 435, subclass 4.
- X. Claims 25 and 26 are drawn to a process for identifying a compound comprising measuring sFRP1 binding activity *in vivo*, and a kit for use in the assay. Classified in class 424, subclass 9.2.
2. The inventions are distinct, each from the other because of the following reasons.
- Inventions II-VI, IX, X, and I are independent or distinct inventions. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, each of groups I-VI, IX, and X is drawn to a different method for modulating stem cells and for drug screening. The different methods use different starting materials, different agents, apply different test criteria,

have different method steps, different modes of operation, and require distinct technical considerations.

Inventions VII and VIII are independent or distinct inventions. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Each group listed above is directed to a structural distinct chemical compound, which are recognized in the art as being distinct from one another because of their diverse chemical structure. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules. Further, given the rebuttable presumption that chemical compounds that are not similar in structure are not presumed to function similarly, the claimed compounds are expected to have different chemical properties, modes of action, different effects, and reactive conditions (MPEP 806.04, 808.01).

Inventions I, V, and VII; or II, VI, and VIII are related as product and process of use, respectively. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used for either a cell culture or treating a patient, i.e. materially different process of using the product. The process for using the sFRP polypeptide as claimed could be practiced with another materially different product, such as a chemical compound identified by invention group IX.

The differences of the Inventions I-X are further underscored by their divergent classification and independent search criteria.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different search criteria, a serious burden is imposed on the Office to perform a complete search of the defined areas in both the patent and non-patent literature if all the groups are examined together. Therefore, the restriction set forth is proper and not to restrict would impose a serious burden in the examination of this application.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not

commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

3. This application contains claims directed to the following patentably distinct species of the claimed invention. Upon election of an invention for examination in this application, further election of a species is necessary. The species is defined as a combination of the following factors:

a. Upon election of one of the inventions I-VI, IX, X, further elect the type of stem cells subject for regulation, or used for treatment such as embryonic stem cells or hematopoietic stem cells;

b. Upon election of one of the invention groups IV-VI, further elect a specific type of disease for treatment, e.g. an autoimmune disease or cancer.

c. Upon election of group X, further elect a species with which the sFRP1 interacts in vivo, and a means for measuring said interaction.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of a, b, and c, for prosecution on the merits to which the claims shall be

restricted if no generic claim is finally held to be allowable. Currently, claims 1-26 are generic, i.e. no single claim is drawn to a particular species.

Each of the listed species is structurally and functionally distinct, and not overlapped in structure search. Thus, a search and examination of anything more than one of such together for patentability would be unduly burdensome to the examiner.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that where a single claim encompasses more than one invention as defined above, upon election of an invention for examination, said claim will only be examined to the extent that it reads upon the elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Dave Nguyen** can be reached on 571-272-0731. The fax numbers for the organization where this application or proceeding is assigned are **703-872-9306**.

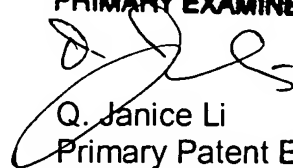
Any inquiry of formal matters can be directed to the patent analyst, **William Phillips**, whose telephone number is (571) 272-0532.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

**Q. JANICE LI, M.D.**  
**PRIMARY EXAMINER**



Q. Janice Li  
Primary Patent Examiner  
Art Unit 1632

*QJL*  
September 25, 2006

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